



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,958	01/03/2006	Jorg Sturzebecher	50125/102001	4120
21559	7590	11/17/2008	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			SZNAIDMAN, MARCOS L	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			11/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No. 10/540,958	Applicant(s) STURZEBECKER ET AL.	
	Examiner MARCOS SZNAIDMAN	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-89 is/are pending in the application.
- 4a) Of the above claim(s) 49-58, 60-62, 66-69, 71-73 and 75-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 46-48, 59, 63, 65, 70 and 74 is/are rejected.
- 7) ☒ Claim(s) 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicant's reply filed on August 18, 2008.

Election/Restrictions

Applicant's election without traverse of Group I (Claims 46-74, 76 and 88-89), compound 53 (Table 3, page 53) as the elected compound of Formula I, and "for preventing blood coagulation at synthetic surfaces" as the elected disease in the reply filed on August 18, 2008 is acknowledged.

Since the elected species for the compound is free of prior art, examination was expanded to the following species: O-(1,1-dimethylethyl)-N-[(phenylmethyl)sulfonyl]-D-seryl-N-[[4-(aminoiminomethyl)phenyl]methyl]-Glycinamide (CAS# 380415-13-4).

Status of Claims

Claims 46-89 are currently pending and are the subject of this office action.

Applicant wrongly stated in the response of August 18, 2008, that the elected species reads on claims 46-48, 59, 63-66, 70 and 74. This is incorrect since the elected species reads only on the following claims: 46-48, 59, 63-65, 70 and 74.

Since the elected species is free of prior art, examination was expanded to the following species: O-(1,1-dimethylethyl)-N-[(phenylmethyl)sulfonyl]-D-seryl-N-[[4-(aminoiminomethyl)phenyl]methyl]-Glycinamide (CAS# 380415-13-4), which reads on the following claims: 46-48, 59, 63, 65, 70 and 74.

Art Unit: 1612

The combined set of claims that read on one or both species and, as a consequence, are presently under examination are: 46-48, 59, 63-65, 70 and 74.

Claims 49-58, 60-62, 66-69, 71-73, and 75-89 are withdrawn from consideration because they don't read on the elected invention and/or any of the two species being examined.

Priority

The present application is a 371 of PCT/EP04/00247 filed on 01/15/2004, and claims priority to foreign application: GERMANY 103 01 300.8 filed on 01/15/2003.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 59 and 74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 59, it is not clear what the phrase "wherein a coupling to a synthetic surface being effected by way of P2" means in the context of the claim. For purposes of examination the above phrase is being ignored.

Regarding claim 74, the phrase "in particular" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Prior Art: counterpart

WO 2001/096366 is the PCT counterpart to US 6841701.

WO 2001/096366 is prior art under U.S.C. 102 (b) as a result of its December 20, 2001 publication date.

US 6841701 is prior art under U.S.C. 102 (e) as a result of its June 15, 2001 priority date.

Because WO 2001/096366 and US 6841701 appear to have identical disclosures, the US patent (US 6841701) is being used as a translation of WO 2001/096366 PCT.

While any reference hereinafter to column and line numbers will be based upon the US patent disclosure, such reference should be interpreted as referring to the corresponding disclosure of the aforementioned PCT counterpart.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-48, 59, 63, 65, 70 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by Sturzebecher et. al. (US 6841701 referring to WO 2001/096366, see above discussion).

Claims 46-48, 59, 63 and 65 recite a method of inhibiting plasma kallikrein and/or factor XIa and/or factor XIIa, said method comprising administering to a patient O-(1,1-dimethylethyl)-N-[(phenylmethyl)sulfonyl]-D-seryl-N-[[4-(aminoiminomethyl)phenyl]methyl]-Glycinamide (Compound A from now on), species representing a compound of formula I being examined).

Claim 74 further limits claim 46, wherein compound A is administered in parenteral form or in enteral form.

Claim 70 limits claim 46 such that the method of claim 46 is used for preventing blood coagulation at synthetic surfaces.

Sturzebecher et al. teach a method of treating thromboembolic disease comprising administering to a patient a factor Xa inhibitor (claim 4 of the US patent). With regards to the Xa inhibitor, the patent teaches the Xa inhibitor includes, but is not limited to, a

Art Unit: 1612

compound which appears to be identical to Compound A claimed in the instant patent application (see column 4, working Example 2, seventh compound from top). Moreover, the patent teaches that the compound is administered in the form of a tablet, coated tablet, capsule, pellet, suppository, solution or patch which are forms of enteral administration (claim 4 of the US patent). Thus, while Sturzebecher et al. do not explicitly teach that the compound inhibits plasma kallikrein and/or factor XIa and/or XIIa, the recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Moreover, although Sturzebecher does not explicitly teach that the method can be used for preventing blood coagulation at synthetic surfaces, the claimed limitation does not appear to result in a manipulative difference between the prior art method since the claimed limitation appears to suggest an intended use of the claimed method does not appear to further limit the patient population or provide any additional steps.

Hence, even though the claims are drawn to a mechanism of action, the claimed method does not appear to distinguish over the prior art teaching of the same or nearly the same method. The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere

Art Unit: 1612

recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. In re Baxter Travenol Labs, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145.

Conclusion

No claims are allowed.

Claim 64 is objected to in part, but only insofar as it relates to the elected species which has been found to be free of prior art, as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim, any intervening claims, and to recite only the elected species.

Claim 64 is withdrawn in part, however, with regard to the non-elected subject matter contained therein.

Correspondence

Art Unit: 1612

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
February 25, 2008

/Brandon J Fetterolf/
Primary Examiner, Art Unit 1642